



PATENT

ATRAUMATIC NEEDLE FOR LUMBAR PUNCTURE

Background

Field of the Invention

This invention relates to needles for use in performing lumbar puncture procedures and, more particularly, to a novel, atraumatic needle apparatus and method for significantly reducing postdural puncture headaches.

The Prior Art

Spinal anesthesia is one of the most frequently employed methods of regional anesthesia. This regional anesthesia is accomplished by the temporary interruption of nerve transmission using a local anesthetic injected into the readily identifiable subarachnoid space. The ensuing anesthesia is predictable, occurs rapidly, and is associated with profound muscle relaxation. The patient may be wide awake, or if preferred, the anesthetic may be supplemented with varying amounts of sedative-tranquilizers. Spinal anesthesia is particularly useful for surgery involving the lower extremities, pelvis, perineum, and lower abdomen.

The spinal column, which surrounds the spinal cord, is formed by a series of vertebrae separated by cartilaginous intervertebral disks and united by a series of ligaments. The body of each vertebra bears the weight of the patient and forms the base of the neural arch. The arch, which surrounds the spinal cord, is made up

1 of a pedicle and lamina on each side. Between the laminae of each  
2 vertebra there is a posterior opening in the vertebral canal. It  
3 is through this opening that a spinal needle is passed when  
4 performing a subarachnoid block.

5 In adults the spinal cord varies in length from 40 to 45 cm.  
6 and ends at various levels of the vertebral column depending on the  
7 age of the patient. In the newborn, the spinal cord extends to the  
8 third lumbar vertebra, but in the adult it usually ends at the  
9 lower border of the first lumbar vertebra because the spinal cord  
10 does not grow as much as the vertebral column. Thirty-one pairs of  
11 symmetrically arranged spinal nerves are each attached to the  
12 spinal cord by an anterior and posterior root. Because the spinal  
13 cord is shorter than the vertebral column, the spinal cord segments  
14 in adults do not lie opposite their corresponding vertebrae. The  
15 spinal nerve roots must travel obliquely in a caudad direction to  
16 reach their respective intervertebral foramina. The roots of the  
17 lumbar, sacral, and coccygeal nerves comprise the cauda equina and  
18 are necessarily the largest and longest in order to reach their  
19 intervertebral foramen. The greater size of these nerve roots  
20 provides a larger surface area to be exposed to the action of local  
21 anesthetics, thus allowing more rapid onset of anesthesia.

22 The spinal cord is covered by three membranes or meninges.  
23 The dura mater (the outermost membrane) is the downward  
24 continuation of the meningeal layer of the cranial dura mater. The  
25 middle of the three coverings, the arachnoid is a thin membrane  
26 closely adherent to the dura mater. The dura and the arachnoid are

1 in such close contact that usually it is not possible to puncture  
2 the dura without also piercing the arachnoid. Nevertheless, on  
3 rare occasions, the tip of the conventional epidural or spinal  
4 needle may accidentally enter the subdural space. Local anesthetic  
5 inadvertently injected into the subdural space will diffuse poorly  
6 and result in inadequate contact with the nerve roots. Poor or  
7 absent anesthesia may ensue. Should subdural placement occur  
8 during an attempted epidural anesthetic, the improper position of  
9 the needle may not be recognized and the injection of an epidural  
10 dose of local anesthetic may result in a much higher block than  
11 anticipated.

12 The innermost membrane, the pia mater, is a thin, delicate,  
13 highly vascular membrane closely adherent to the spinal cord. The  
14 space surrounding the pia is filled with cerebrospinal fluid and is  
15 enclosed externally by the arachnoid. In addition to spinal fluid,  
16 this space contains the spinal nerve roots and the main blood  
17 vessels of the central nervous system. In the cervical and  
18 thoracic regions, the space is only about 3 mm deep, but below the  
19 lower border of the first lumbar vertebra, where the spinal cord  
20 usually ends, the space has a diameter of about 14 to 15 mm.

21 A spinal needle 9 cm long is usually adequate, but longer ones  
22 (10-15 cm) are available for the occasional obese patient or  
23 difficult paramedian approach. A removable, close-fitting stylet  
24 helps stiffen the needle and prevents coring of the tissue.  
25 Commonly, two sizes of spinal needles are used, 22 gauge and 25  
26 gauge. The larger diameter 22 gauge needle is easier to direct and

1 renders the characteristic feel of the various ligaments penetrated  
2 easier to appreciate. However, the incidence of postspinal headache  
3 is increased with the larger needle, particularly if the larger  
4 needle is also equipped with a standard point which is a cutting  
5 bevel.

6 A postdural puncture headache is the most common postoperative  
7 complication of spinal anesthesia. The incidence increases with  
8 the larger spinal needles and those with a cutting bevel at the tip  
9 but decreases with increasing patient age. Postdural puncture  
10 headache also occurs more commonly in women than in men, and more  
11 often in pregnant women than in nonpregnant women. The headache is  
12 positional in that it comes on in the upright position and is  
13 relieved or at least improved in the recumbent position.

14 The causative mechanism of the postdural puncture headache is  
15 believed to be associated with the continuing leakage of  
16 cerebrospinal fluid (CSF) through the dural opening left by the  
17 spinal needle. The leakage of CSF causes a decrease in CSF  
18 pressure which, in turn, produces compensatory cerebral  
19 vasodilation. Bringing the patient into the erect position also  
20 results in traction on the pain-sensitive, dilated blood vessels.  
21 Accordingly, conservative therapy for the postdural puncture  
22 headache consists of bed rest and analgesics.

23 Various preventive measures for the postdural puncture  
24 headache have been advocated. The common practice of keeping the  
25 patient supine for 4 to 24 hours after lumbar puncture has been  
26 shown to be ineffective. For a standard point needle having a

1 cutting bevel at its tip, insertion of the needle with the bevel  
2 parallel to the longitudinal fibers of the dura appears to produce  
3 a smaller rent in the dura with a lower incidence of headache.  
4 Pencil point needles such as the commercially available Whitacre  
5 and Sprotte needles also have a lower incidence of headaches.  
6 These pencil-point needles have a closed pencil point created when  
7 the open end of the needle is swaged closed, as the name implies,  
8 like a pencil point or, more accurately, with a conical apex. This  
9 conical apex is believed to spread, rather than cut, the  
10 predominately longitudinal dural fibers and, on removal of the  
11 needle, the resulting dural hole should be smaller and seal off  
12 more rapidly. Indeed, studies have shown that the incidence of  
13 postspinal headache when a 22 gauge conical apex needle is used is  
14 comparable to that following use of the much smaller 26 gauge,  
15 bevel needle.

16 In an attempt to suitably occlude the dural opening to  
17 minimize leakage of CSF, an available procedure is to create what  
18 is known as a blood patch. This is done by obtaining 10 to 20cc of  
19 blood from the patient and injecting this volume of blood into the  
20 tissue adjacent the puncture site of the spinal needle. This  
21 relatively large volume of blood is required since it is virtually  
22 impossible for the health care professional to exactly position the  
23 blood patch directly over the original puncture site. In effect,  
24 therefore, the blood patch is designed to seal the dural puncture  
25 thereby significantly minimizing the frequency of the postdural  
26 headache.

1           However, even with these improvements, postdural puncture  
2   headache remains a problem although the frequency is significantly  
3   reduced. Further, an adequate flow rate of anesthetic through the  
4   smaller needle is also a concern particularly with the pencil-point  
5   or conical-apex needle since the injection is through a side port  
6   located an incremental distance behind the tip. The placement and  
7   size of this side port is an important feature since it affects  
8   both the distribution of the anesthetic as well as overall strength  
9   of the needle. One particular needle (Sprotte, see Figure 1, Prior  
10   Art) has a relatively long side port which has been found in  
11   certain circumstances to deliver anesthetic to both sides of the  
12   dura since the length of the side port is greater than the  
13   thickness of the dura. Another prior art needle (Whitacre) has a  
14   shorter side port but is cut wider across the needle to overcome  
15   this shortcoming. A wider side port, however, weakens the needle  
16   particularly if the side port is any appreciable distance from the  
17   pencil-point tip.

18           Another disadvantage to the presently available pencil-point-  
19   tip spinal needles is that the sides of the tip are generally  
20   straight in a true cone configuration. Thus, a relatively abrupt  
21   shoulder is formed as a ridge at the juncture between the sloped  
22   sides of the conical tip and the cylindrical side walls of the body  
23   of the needle. It is currently postulated that this relatively  
24   abrupt change in the profile of the needle excessively distorts the  
25   dura and thereby contributes to the presence of a post puncture  
26   hole in the dura.

1 In view of the foregoing, it would be an advancement in the  
2 art to provide a spinal needle having a pencil-like point with a  
3 gently rounded profile to reduce the trauma to the fibers of the  
4 dura. It would also be an advancement in the art to provide a  
5 spinal needle of which the side port has an opening with a cross  
6 sectional area only incrementally larger than the cross sectional  
7 area of the lumen of the hollow needle. It would also be an  
8 advancement in the art to provide a spinal needle having a side  
9 port immediately adjacent the pencil-like point thereby reducing  
10 the length of the moment arm between the tip of the pencil-like  
11 point and the midline of the side port. Such a novel spinal needle  
12 is disclosed and claimed herein.

13  
14 Brief Summary and Objects of the Invention

15 This invention is an atraumatic spinal needle apparatus and  
16 method wherein the needle is provided with a gently curved, pencil-  
17 like point and a side port immediately distal the pencil-like  
18 point. The sides of the pencil-like point are gently rounded to  
19 enable the point to part the fibers of the dura with minimal  
20 trauma. The side port has a cross sectional area incrementally  
21 larger than the cross sectional area of the lumen of the hollow  
22 needle and is located immediately adjacent the pencil-like point in  
23 order to reduce the length of the moment arm between the tip of the  
24 pencil-like point and the midline of the side port. All corners  
25 and edges in contact with the dura, with the exception of the tip

1 of the pencil-like point, are smoothly rounded to reduce trauma to  
2 the dura.

3 It is, therefore, a primary object of this invention to  
4 provide improvements in spinal needle apparatus.

5 Another object of this invention is to provide improvements in  
6 the method of delivering an anesthetic with a spinal needle.

7 Another object of this invention is to provide a spinal needle  
8 with a pencil-like point having gently rounded sides where the  
9 point joins the cylindrical sidewall of the needle shaft.

10 Another object of this invention is to provide a spinal needle  
11 having a side port immediately adjacent the pencil-like point.

12 Another object of this invention is to provide a side port to  
13 a spinal needle, the side port having a cross sectional area that  
14 is incrementally larger than the cross sectional area of the lumen  
15 of the spinal needle.

16 These and other objects and features of the present invention  
17 will become more readily apparent from the following description in  
18 which preferred and other embodiments of the invention have been  
19 set forth in conjunction with the accompanying drawing and appended  
20 claims.

21  
22 Brief Description of the Drawing

23 Figure 1 is an enlarged, plan view of the tip of a prior art  
24 spinal needle shown with portions broken away for ease of  
25 illustration of internal features; and



1        Figure 2 is an enlarged, plan view of the tip of the novel  
2 atraumatic needle for lumbar puncture of this invention shown with  
3 portions broken away for ease of illustration of internal features.  
4

5                    Detailed Description of the Preferred Embodiment

6        The invention is best understood by the following description  
7 with reference to the drawing wherein like parts are designated by  
8 like numerals throughout.  
9

10           General Discussion

11        The spinal needle of the present invention has a modified,  
12 pencil-like point and a side port immediately adjacent the shoulder  
13 portion of the modified, pencil-like point. The term "modified,  
14 pencil-like point" is used herein to distinguish the shape of the  
15 sharpened tip of the spinal needle of this invention from that of  
16 the conventional spinal needle. Conventional pencil points are  
17 constructed as the surface of a right circular cone wherein the  
18 sharpened tip has generally straight, conical sidewalls that define  
19 the surface of the pencil point. This straight sidewall, in turn,  
20 joins the cylindrical surface of the body of the needle in a  
21 relatively abrupt corner formed circumferentially adjacent the  
22 needle tip at the juncture between the pencil point and the needle  
23 body.

24        Referring specifically to Figure 1 (Prior Art) a portion of  
25 the pointed end of a conventional spinal needle is shown generally  
26 at 10 (greatly enlarged) and includes a tip 16, having straight,

1 conical sidewalls 14, a cylindrical needle body <sup>16</sup>12, and a side port  
2 20. The juncture between straight, conical sidewall 14 and  
3 cylindrical needle body 16 is shown as a relatively abrupt ridge or  
4 shoulder 18. The theory behind using this type of pencil-point  
5 needle is that tip 12 is more likely to forcibly part the fibers of  
6 the dura rather than cut them thus leaving a smaller hole that can  
7 be sealed off more readily after the needle has been withdrawn.  
8 However, it is postulated that excessive stretching and even a  
9 limited amount of tearing of the dura occurs when shoulder 18 is  
10 forced through the dura with the result that a hole of sorts  
11 remains in the dura upon withdrawal of the needle. It is this hole  
12 that is believed to be responsible for the post puncture headaches  
13 that have been recorded when using the foregoing pencil-point  
14 spinal needles.

15 On certain occasions, it has also been found that the location  
16 and relative length of side port 20 will result in its being  
17 positioned such that it transects the dura so that a portion of the  
18 anesthetic is delivered on both surfaces of the dura. In effect,  
19 side port 20 is too large in that it occupies too much distance  
20 along the axial length of spinal needle 10. This excessive length  
21 of side port 20 appears to be a compromise between cutting away too  
22 much external wall of spinal needle 10 while at the same time  
23 providing sufficient area to side port 20 to assure adequate flow  
24 of anesthetic through side port 20.

D 25 Regrettably, this <sup>compromise</sup>~~comprise~~ has created the foregoing problem  
26 of straddling of the dura. Further, the placement of side port 20

1 distally from shoulder 18 produces a resulting moment arm 19  
2 represented by the distance between tip 16 and the midline of side  
3 port 20. Moment arm 19 becomes important when tip 16 strikes bone  
4 or is otherwise deflected resulting in a bending force being  
5 imposed on the tip of spinal needle 10. This bending force is  
6 multiplied by the distance through which moment arm 19 can act,  
7 namely, the distance between tip 16 and side port 20. Accordingly,  
8 if spinal needle 10 is going to bend, it will bend at the midline  
9 of side port 20 because of the force of the bending moment exerted  
10 on moment arm 19 coupled with the fact that the presence of side  
11 port 20 significantly reduces the overall mass of spinal needle 10  
12 at that particular location.

13 The size or cross sectional area of side port 20 of this prior  
14 art needle 10 is too large in that the extraneous cross sectional  
15 area contributes nothing to the adequate delivery of anesthetic  
16 through needle 10. In particular, the anesthetic solution is a  
17 liquid and is therefore noncompressible so that the rate of flow  
18 through prior art needle 10 is a function of the pressure exerted  
19 on the anesthetic solution, the viscosity of the anesthetic  
20 solution, and the cross sectional area of the lumen of prior art  
21 needle 10. Only if the cross sectional area of side port 20 is  
22 less than that of lumen 22 will it have an adverse affect on the  
23 rate of flow of the anesthetic solution. This is because the  
24 limiting factor for a non-compressible fluid will inherently be the  
25 cross sectional area of the lumen, not the cross sectional area of

1 side port 20, particularly if this latter cross sectional area is  
2 significantly larger than the cross sectional area of the lumen.

3 Accordingly, simply providing an oversize side port 20 that  
4 has a cross sectional area that is two or three times larger than  
5 the cross sectional area of the lumen provides no improvement in  
6 the flow of the anesthetic solution through prior art needle 10.  
7 Instead, the oversize side port 20 represents a source of a  
8 potential hazard in that the oversize side port 20 removes material  
9 from the side walls of prior art needle 10 which, in turn,  
10 drastically reduces the mechanical strength of the prior art needle  
11 10 particularly as it relates to the residual side walls adjacent  
12 side port 20 and the length of moment arm 19 represented by the  
13 distance between the midline of side port 20 and tip 16. This  
14 latter consideration is important in the event pencil point or tip  
15 16 strikes a bone causing tip 16 to be deflected creating a bending  
16 moment against tip 16 through moment arm 19. If side port 20 is  
17 oversized, this bending moment could cause prior art needle 10 to  
18 bend at its weakest point which will inherently be across the  
19 midsection of side port 20 where the sidewall mass is at a minimal  
20 amount.

21 The negligible advantage provided by the larger cross  
22 sectional area of side port 20 was confirmed by a carefully  
23 conducted experiment. In this experiment the size of side port 20  
24 was measured along with the cross sectional area of lumen 22 of  
25 prior art spinal needle 10. The prior art spinal needle 10  
26 selected for this study was a 24g Sprotte-PAJUNK needle. The

1 internal diameter 17 was measured by a micrometer and was found to  
2 be 0.35 mm. The length 15 and width 13 of side port 20 were found  
3 to be 1.7 mm and 0.32 mm, respectively. Accordingly, the cross  
4 sectional area of lumen 22 was calculated to be 0.096 mm<sup>2</sup> while the  
5 cross sectional area of side port 20 was calculated to be 0.544 mm<sup>2</sup>  
6 which is over five times the cross sectional area of lumen 22 of  
7 prior art spinal needle 10. Clearly, of course, the internal  
8 diameter 17 is the most important factor affecting the flow rate so  
9 that there is absolutely no benefit in having a side port 20 having  
10 an area significantly larger than the cross sectional area of lumen  
11 22.

12 This same prior art spinal needle 10 was then modified by  
13 reducing the area of side port 20 to an area approximately equal to  
14 the cross sectional area of lumen 22. It was found that there was  
15 no difference in the measured flow through either needle. This  
16 study was reported by Aglan, M.Y. and Stansby, P.K. in Anaesthesia,  
17 1992, Volume 47, pp 506-507.

#### 18 19 Detailed Description

20 Referring now to Figure 2, the novel spinal needle of this  
21 invention is shown generally at 30 and includes a needle body 32  
22 having a rounded point 34 terminating in a sharpened tip 36. The  
23 transition zone where the external surface of needle body 32  
24 transitions to rounded point 34 is shown as shoulder 38. A side  
25 port 40 having a width 33 and a length 35 is located adjacent

1 shoulder 38. Interiorly, spinal needle 30 has a hollow lumen 42  
2 having an inside diameter 37.

3 The cross sectional area of lumen 42 is determined by the  
4 well-known mathematical formula for the area of a circle having a  
5 diameter equal to that of inside diameter 37. Accordingly, it is  
6 this area that is the critical factor for flow of anesthetic  
7 solution (not shown) through lumen 42 as long as the area of side  
8 port 40 is at least equal to or greater than the cross sectional  
9 area of lumen 42. In this presently preferred embodiment of this  
10 invention, the relationship of the area of side port 40 to the  
11 cross sectional area of lumen 42 is assured by forming length 35 of  
12 side port 40 as one and a half times inside diameter 37 of lumen  
13 42. For example, if inside diameter 37 is 0.027 inches (0.686mm)  
14 for a 26 gauge spinal needle 10, then length 35 of side port 40  
15 will be 0.0405 inches (1.029mm).

16 At this point it should be pointed out that the area or, more  
17 particularly, the length 35 of side port 40 is shown at its maximum  
18 which is 1.5 times inside diameter 37. Clearly, therefore, in  
19 actual production, spinal needle 30 will have a side port 40 that  
20 has a length 35 that is incrementally less than 1.5 times the  
21 internal diameter 37 so long as the resultant area of side port 40  
22 is equal to or incrementally larger than the cross sectional area  
23 of lumen 42. The mathematical formula representing this  
24 relationship is as follows:

25  
26  
T150X

$$L \times W \geq \frac{\pi D^2}{4}$$

1 Where L is length 35 and W is width 33.

2 The juncture between rounded point 34 and needle body 32 is  
3 configured as a gently rounded shoulder 38 having a very gradual  
4 change in overall dimension diametrically as a function of length  
5 thereby substantially reducing any tendency for a sharp change in  
6 dimension (in contrast, see ridge 18, Figure 1, PRIOR ART). Thus,  
7 any tendency for shoulder 38 to excessively stretch or otherwise  
8 tear the fibers of the dura (not shown) is significantly reduced.  
9 This feature is important not only during penetration but also upon  
10 withdrawal of spinal needle 30 from the dura. In particular, the  
11 fibers of the dura inherently have a certain degree of elasticity  
12 so that they can be stretched to a limited degree by the  
13 penetration of spinal needle 30. The smooth profile of rounded  
14 point 34 in combination with the rounded, gentle profile of  
15 shoulder 38 allows the fibers of the dura sufficient time to  
16 stretch adequately to allow the passage of spinal needle 30 without  
17 exceeding the relatively limited elastic limit of the fibers of the  
18 dura.

19 Importantly and advantageously, I have found that my novel  
20 spinal needle 30 substantially eliminates the residual hole in the  
21 dura and, therefore, the need for the health care professional to  
22 create a blood patch adjacent the place of exit of needle 30 from  
23 the dura (not shown). This surprising result is the direct  
24 consequence of the gentle profile of shoulder 38 which gently parts  
25 the fibers of the dura without cutting them or otherwise damaging

1 them to the extent that a postdural headache does not develop as in  
2 the case of prior art needle 10 (Figure 1).

3 Tip breakage of spinal needle 30 is an extremely important  
4 consideration particularly when one considers the inherent danger  
5 of rounded point 34 breaking off in the immediate vicinity of the  
6 spinal cord (not shown). For this reason moment arm 39, as  
7 measured between the midline of side port 40 and tip 36, is kept as  
8 short as possible consistent with the need to have sufficient  
9 length to rounded point 34 to accommodate parting of the fibers of  
10 the dura as discussed previously. In this presently preferred  
11 embodiment the length of moment arm 39 is held within desirable  
12 limits by placing the leading edge of side port 40 at a position  
13 from tip 36 not to exceed 1.5 times the outside diameter of spinal  
14 needle 30.

15 This placement of side port 40 also provides the advantage of  
16 having the leading edge of side port 40 in the close vicinity of  
17 the curvature region of shoulder 38 thereby incrementally modifying  
18 the total external profile of spinal needle 30 at shoulder 38 as  
19 shoulder 38 passes into the dura (not shown).

## 20 21 The Method

22 Spinal needle 30 is configured with a conventional needle hub  
23 (not shown) and is used in the conventional manner to introduce the  
24 appropriate quantity of anesthetic intrathecal space of the dura.  
25 Importantly, tip 36 along with the gentle profile of rounded point  
26 34 and shoulder 38 parts the fibers of the dura (not shown) without



1 cutting, excessively stretching, or otherwise tearing the same.  
2 Accordingly, after spinal needle 30 is withdrawn the fibers of the  
3 dura are able to return to their original position thereby closing  
4 the hole to preclude excessive leakage of the CSF.

5 From the foregoing, the most important aspect of spinal needle  
6 30 is not what it is but what it virtually eliminates, usually the  
7 creation of a postdural headache after spinal needle 30 has been  
8 withdrawn. This means that the medical professional is required to  
9 spend less time since he/she is able to quickly and easily inject  
10 the appropriate quantity of anesthetic and then remove spinal  
11 needle 30. Further, the anesthetic is delivered more efficiently  
12 since side part 40 occupies less distance along the length of  
13 spinal needle 30 thereby effectively eliminating the risk of  
14 delivery of anesthetic on both sides of the dura.

15 Spinal needle 30 is also safer to use due to the close  
16 proximity of side part 40 to tip 36 resulting in a foreshortened  
17 moment arm 39. Thus, in the event a bone (not shown) is struck by  
18 tip 36, the shorter length of moment arm 39 means that a  
19 substantially greater force will be required to be imposed against  
20 moment arm 39 in order to create a bending action against the end  
21 of spinal needle 30. A force of sufficient magnitude to create a  
22 bending action in prior art needle 10 will not affect spinal needle  
23 30.

24 The present invention may be embodied in other specific forms  
25 without departing from its spirit or essential characteristics.  
26 The described embodiments are to be considered in all respects only

1 as illustrative and not restrictive. The scope of the invention  
2 is, therefore, indicated by the appended claims rather than by the  
3 foregoing description. All changes which come within the meaning  
4 and range of equivalency of the claims are to be embraced within  
5 their scope.

6 What is claimed and desired to be secured by United States  
7 Letters Patent is: